STATE OF _____
DEPARTMENT OF _____
RULE ___(citation)___
_____(rule title)_____

STATEMENT OF FACTS AND CIRCUMSTANCES

[NOTE: The first sentences of the following three paragraphs reflect language in Florida's enabling legislation. These sentences should be modified to reflect, as closely as possible, state statutory language that gives the accrediting agency rulemaking authority, authority to establish a certification program, authority to set criteria for certifying testing laboratories, authority to charge and collect certification fees, and any basis specifying how the fee structure is to be determined.]

Sections _____(legislative statute citations)_____ authorize the Department of _____ to establish a certification and approval program for laboratories that perform analyses of drinking water samples, and to adopt rules for the evaluation and certification of laboratories that perform analyses pursuant to the Safe Drinking Water Act. This certification program fulfills the requirements of Title 40 Code of Federal Regulations Part 141.28 for analyses to be done by approved laboratories, so that __(state)__ could assume primacy for enforcing the federal Act.

In addition, sections ___(legislative statute citations)___ authorize the Department of _____ to establish criteria for the certification of laboratories performing analyses of environmental samples not covered by ____(drinking water statute citations)____ and desiring such certification. The laboratory demand for such certification exists and has grown significantly since its inception in __(year)__. Currently, the Department certifies approximately _____ laboratories for safe drinking water testing and _____ laboratories for environmental testing.

Sections _____(legislative statute citations)_____ authorize the Department to charge and collect certification fees, based on the number of laboratory analytical functions for which certification is sought, that are sufficient to meet the costs incurred in administering and operating these programs. The certification fees have not changed since these Rules were promulgated in __(year)__. At the same time, travel expenses and costs of employing competent personnel have increased. As a result, the existing fees are insufficient to meet the certification program costs.

Nearly every state and territory has assumed primacy for enforcing the federal Safe Drinking Water Act; consequently, each state / territory has established a laboratory certification program. Laboratories analyzing samples from more than one state thus have to be certified in each applicable state. Dealing with different programs can be confusing, frustrating, cumbersome, and expensive to these laboratories. Certification criteria and the scope of methods and analytes for certification vary widely from state to state; in some cases, mutually exclusive requirements are imposed on the laboratories.

To address these concerns, task forces and focus groups at the U.S. Environmental Protection Agency (EPA) have concluded that a nationally-recognized accreditation program run by the existing state certification programs with federal agency oversight would be feasible and beneficial to environmental laboratories. As a result, standards for testing laboratory performance and certification program operation were formulated by consensus with public- and private-sector stakeholders and were adopted in July, 1997 at a national conference.

These standards carry no regulatory authority, and state participation in the national accreditation program is voluntary. Nevertheless, the Department deems that ___(state's)___ participation is worthwhile because laboratory adherence to known, uniform standards produces analytical data with defensible, usable quality, from which sound environmental management decisions can be made.

The acceptance of these consensus standards can instill confidence in the certified laboratory's ability to produce credible results. Therefore, laboratories can be spared the time and expense of undergoing redundant, multiple on-site inspections to meet identical criteria. Furthermore, the competition among laboratories for environmental testing services can be made more equitable by rejecting noncertified laboratory data that has no quality control or validation but was generated solely on low overhead or low cost.

STATEMENT OF PURPOSE AND EFFECT

The proposed rule amendments reflect the intention of the _____(Department)_____ to operate its testing laboratory certification programs according to the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC) and to ensure that certified testing laboratories meet these standards. Accordingly, the existing Safe Drinking Water and Environmental certification programs will be combined into one program. Laboratories will thus only

concern themselves with one application form, analyte sheet, and certificate in completing the accreditation process.

The consensus national standards were formulated with input from federal agencies, state agencies, and the private sector to address the concerns that testing laboratories have with multiple and potentially conflicting state certification requirements. By developing environmental laboratory performance standards that are uniformly implemented nationwide, NELAC hopes to promote the generation of data with known, defensible, usable quality from which sound environmental management decisions can be made, health and safety are enhanced for all public stakeholders, and potential cost savings can be provided.

Under the NELAC standards, laboratories must still meet proficiency testing, on-site assessment, and documented quality system requirements. However, there will be differences in how each requirement is used in the certification process and differences in the timetable and sequence for fulfilling successive requirements.

For proficiency testing, the United States Environmental Protection Agency (EPA) will discontinue offering its Water Supply, Water Pollution, and Discharge Monitoring Report Quality Assurance proficiency samples after calendar year 1998. Under these rule amendments laboratories can choose to analyze these samples free of charge while they are still available or analyze samples from private-sector commercial providers that meet the adopted NELAC standards. Laboratories are therefore no longer restricted to two possible testing rounds per year, as defined by the EPA schedules. A minimum of 30 days is required, though, between successive proficiency testing rounds that can be considered for certification purposes.

Currently, laboratories only have to pass one proficiency sample per year for each available analyte or, for an analyte that is pending certification, pass the proficiency sample from the latest testing round. Under NELAC the timeframe delineation of the state Fiscal Year is eliminated. Thus, although the required pass rate is still at least one proficiency sample per year, any analytes failed on any two consecutive testing rounds will lose certification status, not just the two testing rounds during a particular Fiscal Year. The NELAC standards also contain provisions for judging laboratory proficiency for analytes not present in the test samples, and the required testing will include solid matrices and microbiological specimens that are not currently covered in the EPA programs.

Laboratories are still required to undergo an on-site laboratory inspection by trained Department (or NELAC)

certification officers at least once every two years or before pending analytes and test methods can be added to a laboratory's certification. However, for pending certification, the proposed rule amendments no longer require the laboratory to have an approved quality assurance (QA) plan or demonstrate proficiency beforehand as a prerequisite to the on-site assessment. Thus, even though the laboratory has to pass the pending analyte and/or method on two of the most recent three proficiency testing rounds prior to receiving certification, the option of multiple providers allows for the laboratory to attain certification in a shorter amount of time, once the on-site inspection findings, proficiency testing results, and the documented laboratory quality system have been determined compliant with NELAC standards.

The NELAC standards require laboratories to have documented quality systems. Although the laboratories do not necessarily need to submit their quality systems to this Department for approval, the Department will still encourage laboratories to submit QA plans consistent with NELAC requirements because the submitted plans aid in the preparations for on-site inspections and because some state regulations require QA Plan approval in lieu of laboratory certification.

The NELAC-required Quality System (whether or not submitted to the Department) must contain the following elements:

- Quality policy statement by top management
- Description of the organization and management structure
- Relationships between management, technical operations, and support services
- Description of laboratory document control procedures
- Job descriptions of key staff
- Identification of approved signatories and responsible parties
- Procedures for achieving traceability of measurements
- Listing of test methods being performed
- Mechanisms for ensuring adequate facilities, equipment, and resources
- References to calibrations, verifications, and test procedures used
- Procedures for handling submitted samples
- Reference to major equipment, standards, facilities, reagents, supplies, and services used in conducting tests
- Procedural references to equipment calibration, verification, and maintenance
- Reference to interlaboratory comparisons, proficiency tests, reference materials, and internal quality control in use

- Procedures followed when discrepancies occur or departures from standard operations are needed
- Management arrangements for allowing departures from standard procedures
- Procedures for handling complaints
- Procedures for protecting confidential or proprietary information
- Procedures for audits and data reviews
- Procedures for establishing that personnel are adequately experienced to carry out assigned duties
- Procedures for reporting analytical results
- Table of Contents plus applicable reference lists, glossaries, and appendices

The on-site laboratory inspection will verify that the laboratory has the documentation and records, sufficient to demonstrate adherence to its quality system, and will assess the adequacy of the quality system elements in meeting the NELAC standards. The Department's current use of on-site inspections does attempt to provide an external assessment to a laboratory's quality system as well as verify testing laboratory performance according to approved methods. Nevertheless, the NELAC standards attempt to eliminate any uncertainties that laboratories may have regarding what will be covered during on-site inspections.

The proposed rule amendments will reorganize the scope of certification offered into accreditation tiers that are based on laboratory organizational function, scientific discipline, EPA environmental program, test method, then analyte. To be certified in successive tiers, a laboratory must meet general requirements pertinent to its organizational function (laboratory testing or field sampling), then fulfill successively more stringent requirements relevant to the scientific discipline (biology, chemistry, radiochemistry), EPA regulatory program (CAA, CWA, SDWA, RCRA, CERCLA), approved test methods, and specific analytes that are validated within each method. Because the key tenets of NELAC are the performance of laboratories and certification programs according to prescribed standards, offering the scope of certification in the same format as the NELAC accreditation tiers will facilitate the reciprocal certification of in-state laboratories by other state certification programs.

EPA has promulgated new revisions and updates to the approved methods for air, drinking water, wastewater, solid waste, sludge, and hazardous waste testing. Accordingly, the proposed rule amendments will update references for the test methods approved for certification to include these latest versions and to delete obsolete versions. For some laboratories, this change will result in the deletion of test methods from its

certification. However, the Department will adopt the policy of grandfathering the laboratory's certification to the closest equivalent approved method (if not already certified) and requiring the laboratory either to revise its method number references, Quality System, and data validation techniques to conform to the grandfathered method, or to apply for certification of an alternate approved method.

Because of the increased costs in operating the certification program, the certification fees assessed to laboratories will change. The Department realizes that laboratories soon will have to pay for proficiency samples. Therefore, costs to laboratories will be proportional to the scope of accreditation sought, will be reflective of the state resources needed to assess particular tests, but will be reasonable enough to allow participation by any laboratory that meets NELAC standards, regardless of its size or financial endowment.

[This state-specific paragraph should state what the certification and application fees will be and what other costs are to be assessed (such as on-site inspection expense fees). A summary of the justification for the fee structure can be stated here, but the justification should be described in greater detail in the Economic Impact section.]

SUMMARY OF THE RULE

These rule amendments reorganize the existing Safe Drinking Water and Environmental testing laboratory certification programs into one accreditation program that conforms to National Environmental Laboratory Accreditation Conference (NELAC) standards. Under these standards, testing laboratories must meet proficiency testing, quality system, and on-site assessment requirements that have been formulated and ratified by representatives from federal government agencies, state certification programs, and participating testing laboratories. The existing certification categories are transformed into tiers of accreditation based on scientific testing (biology, chemistry, radiochemistry), environmental monitoring program (SDWA, CWA, RCRA, CERCLA, CAA), test methods, and contaminant analytes. Accordingly, the certification fees are revised to reflect the cost of certifying testing laboratories more accurately.

ECONOMIC IMPACT STATEMENT

(1) Estimate of Cost to Implement

The Department of _____ will incur _____ in costs to train its Laboratory Certification Officers according to

the adopted NELAC standards, once this training becomes available. This cost estimate is based on training ____ Officers with one week of general NELAC training and up to three weeks of specialized training, at $1500 per week.

In order to promulgate this rule, the Department will incur administrative costs of _____, as follows:

Workshops	_____
Postage	_____
Publication costs	_____
Court Reporter	_____
Printing of rules	_____

(2) Cost or Benefit to Persons Directly Affected

The cost changes to pending and certified testing laboratories will occur in three areas: certification fees, on-site inspection fees, and proficiency test sample costs.

[This state-specific paragraph should contain detailed information about what the certification fees will be and the changes relative to the old fee structure for testing laboratories of the following sizes:

(1) Small laboratories performing only Drinking Water microbiology analysis or supporting only CWA NPDES permit compliance work.

(2) Intermediate-size laboratories who typically perform only SDWA and CWA microbiology, metals, and general chemistry (gravimetric, colorimetric, titrimetric, potentiometric) testing.

(3) Full-service testing laboratories that typically perform microbiology, metals, general chemistry, volatile organics, extractable organics, and pesticides/herbicides/PCB’s testing for SDWA, CWA, RCRA, and CERCLA programs.

(4) Specialized testing laboratories, which typically conduct testing in one specific area (e.g. Asbestos, Dioxin, Bioassay, Radiochemistry).

(5) Permitted source air emissions facilities, ambient air monitoring networks, and continuous emissions monitoring networks that may fall within the scope of testing certification requirements for the first time.]

Typical, existing inspection expense fees for out-of-state laboratories range within $_____ since the travel times and distances are greater than for in-state laboratories.

However, these amounts for an out-of-state laboratory can be reduced if some or all of its certification can recommended through reciprocity from other NELAC-subscribing and NELAC-compliant state certification programs that are nearer to the laboratory's physical location.

Although not an explicit part of these rule amendments, the costs of obtaining commercial proficiency samples when EPA discontinues its programs will impact testing laboratories in 1999. Since laboratories must participate in at least two testing rounds per year, yearly cost estimates are $200-300 for drinking water microbiology, $450-900 for drinking water metals and general chemistry, $800-1600 for drinking water organic contaminants, $500-1500 for wastewater metals and general chemistry, $600-1200 for wastewater organics, and $750-1500 for solid-phase samples. These costs will be higher if the laboratory must participate in additional testing rounds in order to demonstrate the necessary proficiency.

The financial benefits of certification to testing laboratories are indirect and intangible. In practice, laboratories use the certification credentials in their marketing and public relations to attract potential clients. In some cases, customers do require a laboratory to be certified as a condition for condition for doing business. The documented Quality System required under NELAC should help laboratories reduce costs by eliminating systematic errors and the need for repeat sample analysis. Increased costs associated with data defensibility and legal scrutiny should also be minimized if the laboratory diligently follows its Quality System and the approved test methods as documented. The certification process also serves as an external assessment of the laboratory's quality practices.

(3) Estimate of Effects on Competition and the Open Market

The proposed rule amendments are not expected to have any effect on competition and the open market. However, if laboratory performance according to NELAC standards enhances the acceptability and validity of testing data, then the public and regulatory agency demand for services from certified laboratories should eliminate competition from unqualified laboratories that underbid certified laboratories for contracts.

(4) Data and Methods Used in Making Above Estimates

Data on the revenues and expenses for the trust fund established for the Department's laboratory certification program is available through the state accounting system. Revenues are derived from certification fees, application fees, and out-of-

state inspection expense fees. The majority of expenses are for staff salaries and benefits, travel expenses, and administrative overhead. The previous increase in certification fees ____ years ago was sufficient to create a small surplus. However, the rising costs of state benefit programs and administrative expenses have erased this surplus, and the certification program is currently operating at a deficit.

With the added responsibility of operating the certification program according to the NELAC standards and with the proposed reorganization of the scope of certification into the NELAC tiers of accreditation, the Department has assessed the person-hours for each job classification involved with processing the application form, reviewing proficiency test results, approving Quality Systems, conducting on-site laboratory inspections, and issuing certification credentials. The Department has also considered the costs associated with training the on-site assessors in the NELAC standards, newly approved analytical techniques, additional regulatory programs (e.g. CAA), and EPA's proposed Performance-Based Measurement Systems in devising the new fee structure. Under these considerations and circumstances, the proposed fees are deemed the most reasonable and equitable when considering the substantial interests of both small laboratories and large laboratories, the Department's efforts for each aspect of the certification process relative to the scope of analytes and methods sought, and the revenues needed to cover these projected costs.

(5) Impact on Small Business

In considering the proposed fee structure, the Department considered that a given increase in costs to laboratories could have a disproportionate impact on smaller laboratories, whose budgets are smaller and are often beyond the laboratory section's ability or authority to control. In addition, some smaller laboratories' expenses must be projected, planned, and budgeted for the next Fiscal Year; the Department thus considered the longer timeframe with which smaller laboratories may need to handle certification cost changes.

In effect, the full-service testing laboratories will actually be subsidizing the certification fees of smaller laboratories because a fixed amount of staff time is spent reviewing a laboratory's organization and Quality System regardless of size. Also, the marginal time for reviewing additional analytes and test methods is proportionally smaller than the fees that full-service organizations pay relative to the small laboratories. Nevertheless, the usual comments from larger laboratories indicate no objection to this disparity as long as the smaller laboratories are assessed according to the NELAC

standards with the same level of scrutiny as the larger laboratories, and as long as the competitive playing field is level with respect to smaller laboratories not receiving tax revenues, cost subsidies, or other preferential treatments that larger laboratories have no access to, in bidding for the same service contracts.

FEDERAL COMPARISON STATEMENT

The Safe Drinking Water Act (SDWA) is the only environmental regulation that requires analyses by approved laboratories. These regulations only specify absence of fraud, satisfactory analysis of proficiency samples, and use of approved test methods as requirements for approval. EPA has published a “Manual for the Certification of Laboratories Analyzing Drinking Water” (now in the 4th Edition), which EPA uses to inspect the Principal State Laboratory and encourages state certification programs to use for other laboratories. However, since this EPA Manual, the NELAC Standards, and laboratory certification for other environmental monitoring programs have no regulatory force, a comparison of these rule amendments to the federal requirements does not exist.